

Remarks

Status of Claims

Claims 1 and 3-16 were rejected. Claims 1, 9, and 10 have been amended. The amendments to the claims are being made merely to clarify the invention. All of the amendments are fully supported by the specification, claims, and figures as originally filed. No new matter is believed or intended to be involved.

Claim Objections

Claim 1 was objected to for including the term "and" at the end of element f., and for failing to include the term "and" at the end of element g. Accordingly, claim 1 has been amended to strike the occurrence of "and" at the end of element f., and to add the term "and" at the end of element g. Applicant therefore submits that the objections have been obviated, and respectfully requests that the objections be withdrawn.

§103 Rejections

Claims 1 and 3-16 were rejected under 35 U.S.C. §103(a) as being obvious over Ritchart et al. (U.S. 6,428,486) in view of Banik et al. (U.S. 5,601,585). Under MPEP 2143.03, in order to establish a *prima facie* case of obviousness, the prior art reference or combination of references must teach or suggest all of the limitations of a claim. A *prima facie* case of obviousness also requires that there be some teaching, suggestion, or motivation to modify the references either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. MPEP 2143.01. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP 2143.01. *Actual evidence* of a suggestion, teaching or motivation to combine prior art references must be shown. *In re Dembiczak*, 50 USPQ2d 1614 (Fed.Cir. 1999). Broad *conclusory statements*, standing alone, simply *are not evidence*. *Id.* Motivation to combine or modify will be lacking if the art teaches away from a claimed combination. MPEP 2145. For at least the reasons set forth below, Applicant respectfully submits that the combined art of record fails to render present claims 1 or 3-16 obvious.

Applicant submits that the art of record fails to teach or suggest all of the limitations recited in each independent claim in accordance with MPEP 2143.03. For instance, Applicant notes that amended independent claim 1 recites a means at the distal end of the needle for causing the push rod to turn 180 degrees thereby reversing its direction of movement "from a distal direction to a proximal direction," whereby said push rod end enters said cutter "from the distal end of the cutter." These limitations, among others recited in amended claim 1, are neither taught nor suggested by the combined art of record. Indeed, to the extent that Banik et al. teaches any kind of push rod, it fails to teach or even remotely suggest the distal-proximal reversal of direction as recited in amended claim 1; and the entry of the push rod in Banik et al. is from the proximal end of the cutter – not the distal end of the cutter as recited in amended claim 1. Applicant therefore submits that the combined art of record fails to teach or suggest all of the limitations of amended claim 1 in accordance with MPEP 2143.03. Accordingly, Applicant respectfully submits that the combined art of record fails to render present claim 1 obvious in accordance with MPEP 2143, and respectfully requests that the rejection be withdrawn.

Amended independent claim 9 recites a flexible push rod being provided in a second lumen that is external to and parallel to a first lumen, with a cutter being provided in the first lumen, and with at least a portion of the push rod being "external and parallel to the cutter." These limitations, among others recited in amended claim 9, are neither taught nor suggested by the combined art of record. Indeed, to the extent that Banik et al. teaches a push rod, such a push rod is located within a cutter – not in the separate lumen as recited in amended claim 9. Applicant therefore submits that the combined art of record fails to teach or suggest all of the limitations of amended claim 9 in accordance with MPEP 2143.03. Accordingly, Applicant respectfully submits that the combined art of record fails to render present claim 9 obvious in accordance with MPEP 2143, and respectfully requests that the rejection be withdrawn.

Amended independent claim 10 recites a distal end of a flexible push rod being adapted to "push a tissue sample in a proximal direction into the hollow cutter in response to distal pushing on a proximal portion of the flexible push rod." These limitations, among others recited in amended claim 10, are neither taught nor suggested by the combined art of record. Indeed, to the extent that Banik et al. teaches a push rod, such a push rod does not push a tissue sample proximally in response to distal pushing on the push rod as recited in amended claim 10. Applicant therefore submits that the combined art of record fails to teach or suggest all of the limitations of amended claim 10 in accordance with MPEP 2143.03. Accordingly, Applicant respectfully submits that the combined art of record fails to render present claim 10 obvious in accordance with MPEP 2143, and respectfully requests that the rejection be withdrawn.

Even if all of the references in combination taught or suggested all of the limitations recited in the amended claims, the Office has failed to establish the motivation to modify or combine the teachings of the references as required by MPEP 2143, and has instead relied upon impermissible hindsight reconstruction in declaring the claimed invention obvious. Indeed, MPEP 2143.01 admonishes that "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." (emphasis in original). *Actual evidence* of a suggestion, teaching or motivation to combine prior art references must be shown. *In re Dembiczak*, 50 USPQ2d 1614 (Fed.Cir. 1999). Broad *conclusory statements* regarding the teaching of references, standing alone, simply *are not evidence*. *Id.* Rather than being based in evidence in the record, the motivation provided by the Office appears to be based solely on a subjective opinion of an individual examiner rendered nearly 4 years after the priority/filing date of the present application. This falls far short of the requirements of MPEP 2143.01. *See In re Dembiczak*, 50 USPQ2d 1614 (Fed.Cir. 1999). Ultimately, the Office has failed to provide the requisite *evidence* in the prior art suggesting the desirability of the combinations claimed herein. Because the motivation required by MPEP 2143.01 is lacking, Applicant respectfully requests that the rejections be withdrawn.

Applicant further notes that the dependent claims include additional limitations not taught or suggested in the art of record, thus forming independent basis for non-obviousness.

Conclusion

While several distinctions have been noted over the art of record, Applicant notes that there are several other limitations recited in the present claims that are neither taught nor suggested by the art of record. Applicant expressly reserves all rights and arguments with respect to distinctions not explicitly noted herein. In addition, to the extent that the amendments constitute a narrowing of the claims, such narrowing of the claims should not be construed as an admission as to the merits of the prior rejections. Indeed, Applicant traverses the rejections and preserves all rights and arguments. To the extent that any particular statement or argument by the Office in the pending Office Action has not been explicitly addressed herein, the same should not be construed as an acquiescence or admission by the Applicant that such statements or arguments by the Office are accurate or proper.

Based on the foregoing, all pending claims are in a condition for allowance. Accordingly, Applicant respectfully requests reconsideration and an early notice of allowance.

Respectfully submitted,

/Andrew B. Ulmer/

Andrew B. Ulmer

Reg. No. 57,003

Johnson & Johnson

One Johnson & Johnson Plaza

New Brunswick, NJ 08933-7003

(513) 337-3535